

Remarks

Claims 24 and 28-38 are currently pending in the subject application. The Applicants respectfully request reconsideration of these claims in view of the following arguments

112 Rejection of Claim 36

Claim 36 has been rejected under 35 USC 112, 2<sup>nd</sup> paragraph, for being indefinite. In particular the Examiner has questioned whether the claim covers a microspore or a regenerated plant.

Claim 36 clearly requires that the microspore be regenerated into a plant that contains the genetic mutation. The claim in its present form covers a regenerated plant. The Applicants will amend Claim 36 into independent form if deemed necessary by the Examiner. Applicants respectfully request that this rejection be withdrawn.

112 (2<sup>nd</sup> Paragraph) Rejection of Claims 24, and 28-38

Claims 24 and 28-32 have been rejected under 35 USC 112, 1<sup>st</sup> paragraph, for failing to comply with the written description requirement. This rejection is respectfully traversed.

The written description requirement is clearly met by Claims 24 and 28-32. First, Claim 24 is an original claim and is thereby part of the written description of the invention. Second, the Specification teaches in detail how to practice the presently claimed invention as discussed in the Applicants prior response. The Examiner quotes *Brenner v. Manson*, 383 U.S. 519 (1966) which states, "The basic quid pro quo contemplated by the Constitution and the Congress for granting a monopoly is the benefit derived by the public from an invention with substantial utility...." The Applicants stop there in the famous US Supreme Court decision. The Applicants invention contributes to the state of art that mixed duplex oligonucleotides (MDON) can be used to form a mutation in the genome of a microspore. A written description of that broad invention cannot be disputed. To come back and say that the Applicants should be limited to only the specific MDONs specifically denoted in the Specification is inconsistent with *Brenner* in that the disclosure of only a small number of MDONS coupled with the teachings of broad applicability to change any nucleotide

in any microspore would then allow anyone else to make their own MDON and change any desired nucleotide that is not specified in the Applicants Specification. This is not quid pro quo. Applicants would consider that highway robbery. How could the patent laws limit the patent claims to a handful of mutations and then allow the rest of the world to copy the invention and make any change to any gene in any microspore? That's not what the Supreme Court intended in Brenner. The Applicants have explained in detail their invention, namely, the use of MDONs to make mutations in microspores. Clearly, the written description requirements have been met.

For the above reasons Applicants respectfully request that the present 112 rejection of Claims 24 and 28-32 be withdrawn.

112 (1<sup>st</sup> Paragraph) Rejection of Claims 24, and 28-38

Claims 24 and 28-32 have been rejected under 35 USC 112, 1<sup>st</sup> paragraph for failing to comply with the enablement requirement. This rejection is respectfully traversed.

The Applicants reinforce their argument comparing the prior art Kmiec '350 and '181 patents in support of enablement. Additionally, the Kochevenko et al article cited by the Examiner supports the Applicants arguments for enablement. Kochevenko and his colleagues were successful in making the desired mutations. At page 174 (abstract) of Kochevenko et al it states: "We describe the **SUCCESSFUL** in vivo targeting of endogenous tobacco (*Nicotiniana tabacum*) ALS genes using chimeric RNA/DNA and all-DNA oligonucleotides at two different locations. (emphasis added). Gene repair technology in general always results in a desired mutation (phenotype) but as the art recognizes there are also other mutations that may occur. Sometimes these other non-desirable mutations don't occur as seen in the target gene ALS-1719 in Table 1 of Kochevenko et al where only the desired change was observed. This is not an argument for lack of enablement. As seen in by Kochevenko et al they obtained the desired mutations and also observed some others in certain lines of plants. Likewise, in the chemical arts chemical reactions can have by-products, impurities and other anomalies that do not yield the desired compound. This does not mean that a chemical process isn't enabled because it does not result in a 100% yield. In the biotechnology arts involving gene manipulations the skilled artisan ALWAYS will conduct routine experiments to check that the gene manipulation is the desired one. This art is sophisticated and routine experimentation is always done to verify results. Because of this it doesn't matter that sometimes

sometimes some aberrant results may occur because the skilled artisan will easily confirm the desired mutation. Claims 24 and 28-38 are enabled. Withdrawal of this rejection is respectfully solicited.

#### 102 Rejection of 30-32 and 36-38

Claims 30-32 and 36-38 have been rejected under 35 USC 102 as being anticipated by Hawkes et al. This rejection is respectfully traversed.

As set forth before previously by the Applicants, Hawkes et al discloses gene repair in pollen versus the gene repair of microspores in the present claims. The current claim limitations require that the genomic mutation be made by gene repair of the microspore. These claims do not cover mutations made in pollen. For these reasons Hawkes et al cannot support a 102 rejection. Withdrawal of this rejection is respectfully requested.

#### 103 Rejection of Claims 24 and 28-38

Claims 24 and 28-38 have been rejected under 35 USC 103 as being unpatentable over Kmiec '181 and Fennell et al. This rejection is respectfully traversed.

The presently rejected claims are not obvious in view of the cited art. The gene repair reference (Kmiec '181) cannot be properly combined with the microspore transformation reference (Fennell et al) because of the various differences not only in the physical and chemical properties between large polynucleotides used in transformation and the small fragile oligonucleotides used in gene repair but also the differences between gene repair and transformation themselves. The only reasonable conclusion that could be made regarding these disparate arts would be to say that it would be "obvious to try" the methodologies taught by Fennell et al (transformation) with the gene repair taught by Kmiec '181. However, "obvious to try" is not the proper standard for obviousness under 35 USC 103. The Examiner is incorrect in stating that there would be a "reasonable expectation of success" given the teachings of Fennell et al. Nothing could be further from the truth. There is absolutely no teaching by Fennell et al that would allow one of ordinary skill in the art to expect success in making mutations in microspores employing MDONs.

For the above reasons, Claims 24 and 28-38 are not obvious over Kmiec '181 in view of Fennell et al. Withdrawal of this rejection is respectfully solicited.

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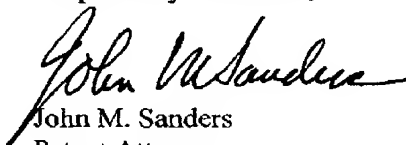
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In view of the foregoing remarks, the Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The Applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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